

**NEW YORK STATE
DEPARTMENT OF FINANCIAL SERVICES
FIRST AMENDMENT TO
11 NYCRR 451
(INSURANCE REGULATION 221)**

REGISTRATION OF PHARMACY BENEFIT MANAGERS

I, Adrienne A. Harris, Superintendent of Financial Services, pursuant to the authority granted by Financial Services Law sections 102, 201, 202, 301, 302, and 306; Insurance Law sections 301; and Public Health Law section 280-a, after consultation with the Commissioner of Health, do hereby promulgate, as an emergency measure, the following First Amendment to Part 451 of Title 11 of the Official Compilation of Codes, Rules and Regulations of the State of New York (Insurance Regulation 221), to take effect upon the filing of the Notice of Emergency Adoption with the Secretary of State, to read as follows:

(Matter In Brackets Is Deleted; New Matter Is Underlined)

Section 451.3 is amended as follows:

Pursuant to the authority granted to the superintendent by Public Health Law section 280-a(2)(g) to limit the duties, obligations, requirements and other provisions relating to pharmacy benefit managers under Public Health Law section 280-a(2), the duties, obligations and requirements contained in Public Health Law section 280-a(2)(b), (c), (d), (e), and (f) shall not apply to pharmacy benefit managers until January 1, [2023] 2024.

**Statement of the Reasons for the Adoption of the Emergency Measure
Amending 11 NYCRR 451 (Insurance Regulation 221)**

The New York Legislature passed Chapter 828 of the Laws of 2021 on December 31, 2021, requiring the New York State Department of Financial Services (“Department”) to regulate pharmacy benefit managers (“PBMs”) operating in New York, including requiring PBMs to have certain duties, accountability, and transparency obligations to New York health plans. The legislation was subsequently amended by Chapter 128 of the Laws of 2022, which went into effect on February 24, 2022.

Specifically, the legislation amended Public Health Law section 280-a(2) to require PBMs to disclose and report certain information to health plans related to the pharmacy benefit management services they provide to their health plans, and to provide an accounting of all funds received by the PBM for pharmacy benefit management services attributable to the health plan. Authorized by Public Health Law section 280-a, the Superintendent of Financial Services (“Superintendent”), in consultation with the Commissioner of Health, promulgated 11 NYCRR Part 451 (Insurance Regulation 221), which implements provisions defining, limiting, and relating to the duties, obligations, requirements, and other matters relating to PBMs contained in Public Health Law section 280-a.

Given the impending expiration of the moratorium imposed by 11 NYCRR 451 (Insurance Regulation 221) on the duties, obligations, and requirements of PBMs, and the need for additional guidance and regulations with respect to the PBM reporting provisions set forth in Public Health Law Section 280-a(2), this emergency amendment is necessary to maintain the status quo and provide certainty to the industry until fully promulgated regulations are effectuated so that PBMs subject to the statutory requirements have clear guidance and detailed instructions on the application of, and how to comply with, those Public Health Law section 280-a requirements .

This amendment is necessary to ensure that there is no disruption in the management or administration of prescription drug benefits by PBMs for New York health plans, which management or administration is integral to the public health, safety, and general welfare of the New York health plan beneficiaries. In the absence of this amendment, New York health plan beneficiaries could be prevented from accessing necessary prescription drugs, which could result in serious health and safety consequences for such beneficiaries.

Signed copy filed with Department of State
Adrienne A. Harris
Superintendent of Financial Services

Date: June 23, 2023

KATHY HOCHUL
Governor



ADRIENNE A. HARRIS
Superintendent

CERTIFICATION

I, Adrienne A. Harris, Superintendent of Financial Services, do hereby certify that the foregoing is the First Amendment to Part 451 to Title 11 of the Official Compilation of Codes, Rules, and Regulations of the State of New York (Insurance Regulation 221), entitled "Registration of Pharmacy Benefit Managers", signed by me on June 23, 2023, pursuant to the authority granted by Financial Services Law sections 102, 201, 202, 301, 302, and 306; Insurance Law sections 301; and Public Health Law section 280-a, after consultation with the Commissioner of Health, to take effect upon the filing of the Notice of Emergency Adoption with the Secretary of State.

Pursuant to State Administrative Procedure Act Section 202(6), the First Amendment to Part 451 to 11 NYCRR (Insurance Regulation 221) is being promulgated as an emergency measure. A statement of the specific reasons for the finding of the need for emergency action is attached.

Signed copy filed with Department of State
Adrienne A. Harris
Superintendent of Financial Services

Date: June 23, 2023